

Medical Device and Drug Safety Programs

Licensing Requirements

On January 1, 2013, a new law took effect. AB 1277 (Assembly Bill 1277-Hill) was signed into law by Governor Edmund G. Brown, Jr. and describes the new licensing process for drug and medical device manufacturers.

The department will continue to license medical device and drug manufacturers, however, under the new law, amended section 111635 of the Health and Safety Code (H&SC) requires each place of business to provide evidence of ownership and any of the following:

- (1) The place of business is operating pursuant to a valid biologics license issued by the United States Food and Drug Administration in compliance with Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262).
- (2) The place of business is operating with a valid establishment registration pursuant to Section 510 of the federal act (21 U.S.C. Sec. 360). This documentation shall include an attestation from an officer of the place of business that a federal inspection was completed within the two years prior to the date of attestation.
- (3) The place of business is operating in compliance with audits conducted pursuant to the International Standards Organization (ISO) 9000 series, ISO 13485:2003 quality management systems standards, ISO 15378:2006 quality management systems standards, pursuant to Parts 210 and 211 of Title 21 of the Code of Federal Regulations, or pursuant to Part 820 of Title 21 of the Code of Federal Regulations.
- (4) The place of business is operating pursuant to an approved investigational new drug issued by the federal Food and Drug Administration pursuant to Section 312.20 of Title 21 of the Code of Federal Regulations or pursuant to an approved investigational device exemption issued by the federal Food and Drug Administration pursuant to Section 812.20 of Title 21 of the Code of Federal Regulations.

If the department receives documentation that satisfies the requirements of subdivision (a) above, the department shall not inspect the place of business prior to issuing a license required by H&SC Section 111615. If the department does not receive the documentation required, the department shall inspect the place of business prior to issuing a license as required by H&SC Section 111615.